

Atty. Dkt. No. EPI3007E
(071344-0305)

REMARKS

After amending the claims as set forth above, claims 53, 56, 63-65, 67, 68, 76 and 85-92 will be pending in this application.

Claims 53 and 85 have been amended to clarify the invention for better understanding by the Examiner. No new matter has been added by these changes. Furthermore, Applicant submits that the amendments do not limit the claim scope.

Applicants have identified herein that the status of claim 66 is "cancelled."

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 85 and 86-92 have been rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking written description for the phrase "at least a portion of the variable region of an immunoglobulin light chain" and "wherein said light chain and said heavy chain are the product of a lymphoid cell producing an antigen-specific immunoglobulin." The Examiner alleges that this phrase introduces new matter that goes beyond the specification which is alleged to cover only specific antibody fragments previously known in the art. The rejection is respectfully traversed.

Relevant Law

To satisfy the written description requirement of 35 U.S.C. § 112, ¶1, the specification must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the applicant was in possession of the claimed invention. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991). Compliance with the written description requirement is essentially a fact-based inquiry that will necessarily vary depending on the nature of the invention claimed. *See, e.g., Enzo Biochem. Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1324, 63 U.S.P.Q.2d 1609, 1612 (Fed. Cir. 2002).

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Response to statements by the Examiner

The Examiner argues that the claim limitations “at least the antigen specific portion of an immunoglobulin light chain” and “wherein said light chain and said heavy chain are the product of a lymphoid cell producing an antigen-specific immunoglobulin” recited in claim 85 do not find support in the specification as originally filed.” Paper No. 0604, page 3. Applicant wishes to point out that the claim language “at least the antigen specific portion of an immunoglobulin light chain” is explicitly or implicitly disclosed in several sections of the application. For example, the specification at page 11, lines 1-18, discloses full length and modified immunoglobulin molecules including and immunoglobulin Fv fragment which is “a multimeric protein consisting of the immunologically active portions of an immunoglobulin heavy chain variable region and an immunoglobulin light chain variable region covalently coupled together and capable of specifically combining with antigen.” (emphasis added). One of ordinary skill would have been clearly understood the phrase “immunologically active portions” in the above to refer to “antigen specific portion” of the light and/or heavy chain variable region. Further support is found at page 15, lines 28-33, wherein reference to an Fv is indicated to reflect “at least a portion of an immunoglobulin light chain variable region.” Clearly implicit in this phrase is that the portion be the “antigen specific,” as evidenced by the teaching that it form a binding site for “specific for a preslected or predetermined antigen.” *Id.* at line 33. Thus, the application as filed clearly supports the phrase “at least the antigen specific portion of an immunoglobulin light chain.”

Furthermore the applicant wishes to further point out that the claim language “wherein said light chain and said heavy chain are the product of a lymphoid cell producing an antigen-specific immunoglobulin” as recited in claim 85 is disclosed in the application, for example, at page 17, lines 1-23. The cited section describes an approach for isolating antibody producing lymphoid cells from an immunized vertebrate (mouse) spleen and isolating the genes encoding the immunoglobulin heavy and immunoglobulin light chain. Thus, one of ordinary skill in the art would understand that the antigen specific portion of the light chain of an antigen specific

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immunoglobulin can be obtained from such lymphoid cells. Also, the hybridoma producing the antibody 6D4 which is described in Example 1 (beginning at page 52) also exemplifies a lymphoid cell that produces an antigen-specific immunoglobulin. Those of ordinary skill would appreciate that such lymphoid cells are starting points for obtaining "at least the antigen specific portion of an immunoglobulin light chain" for expression in plant cells.

In view of the above, it is respectfully submitted that the specification provides more than adequate written support for the claim language. Accordingly, reconsideration and withdrawal of the rejection is requested.

REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The claims have been variously rejected under 35 U.S.C. § 112, Second Paragraph. Reconsideration of the rejections is respectfully requested in view of the amendments and remarks herein.

Relevant Law

When determining definiteness, the proper standard to be applied is "whether one skilled in the art would understand the bounds of the claim when read in the light of the specification." *Credle v. Bond*, 30 USPQ2d 1911, 1919 (Fed. Cir. 1994). Recognizing that the English language is not always precise, the settled law has established that the essential inquiry in a definiteness analysis is whether the claims set out and circumscribe the claimed subject matter with reasonable particularity. *See, e.g.,* MPEP § 2173.02; *see also, Miles Laboratories, Inc. v. Shandon, Inc.*, 27 USPQ2d 1123, 1127 (Fed. Cir. 1993) ("If the claims read in the light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.") (emphasis added). Definiteness is not analyzed in a vacuum, but in light of the content of the specification, and with the knowledge available to the skilled artisan.

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(1) Claims 53, and claims 63-65, 67-68 and 76 have been rejected under 35 U.S.C. §112 as being indefinite because the recitation "said plant cell" in line 12 is unclear as to whether the "said plant cell" refers to "A plant cell" in the preamble of the claim, or whether "said plant cell" refers to "a plant cell" in lines 10-11 of the body of the same claim. Applicants respectfully submit that the claim is clear as written. However, to avoid any possible ambiguity, line 4, in section b) of the claim now recites "said plant cell." Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

(2) Claims 53, 85 and claims 56, 63-65, 67-68, 76 and 86-92 have been rejected under 35 U.S.C. §112, second paragraph, because the recitation "wherein said plant cell does not contain nucleotide sequence encoding said immunoglobulin heavy chain" is allegedly unclear as to whether "the plant cell does not contain any nucleotide sequence encoding an immunoglobulin heavy chain", or "whether the plant cell does not contain the nucleotide sequence encoding the specific heavy chain from the particular antigen-specific immunoglobulin that the light chain is obtained from (claim 53) or the antigen specific portion of the light chain is capable of assembly (claim 85).

As noted by the examiner, the instant application is restricted to plant cells containing nucleotide sequences encoding at least the antigen specific portion of the light chain immunoglobulin polypeptides only. The claims have been amended to clarify that nucleic acid encoding a heavy chain is not included. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

(3) Claim 85 and claims 86-92 dependent thereon, have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite because the recitation "said antigen specific portion of the light chain being capable of assembly with an immunoglobulin heavy chain." The examiner argues that the capacity of an immunoglobulin light chain to assemble with an immunoglobulin heavy chain resides outside of the antigen specific portion of the light chain.

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The Applicant respectfully disagrees with the examiner that the capacity of assembly resides outside the antigen specific portion of the light chain. For example, the immunoglobulin light chain and heavy chain variable regions are portions of the light and heavy chain that are known to associate with each other (or with the full length chain of the other) as in the case of an Fv (or sFv) fragment. Such molecules are well known in the art and are described in the application at page 11, lines 13-18. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

(4) Claim 88 has been rejected under 35 U.S.C. §112 as being allegedly indefinite because it lacks a transitional phrase between "said nucleotide sequence" and "a variable region". Applicant has amended the claim to clarify that the nucleotide sequence "encodes" a variable region and at least a portion of the constant region of an immunoglobulin light chain. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is urged to contact the undersigned by telephone to address any outstanding issues standing in the way of an allowance.

Respectfully submitted,

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